



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 1, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 63761-I/
Sterilex Ultra Disinfectant Cleaner Solution I
DP Barcode: D311974

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell, PM 33 / Tony Kish
Regulatory Management Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

3/1/05

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: The Sterilex Corporation

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
N-Alkyl dimethylethylbenzyl ammonium chloride	3.00
n-Alkyl dimethylbenzyl ammonium chloride	3.00
Hydrogen Peroxide	6.30
<u>Other Ingredient(s):</u>	<u>87.70</u>
Total:	100%

- I **BACKGROUND:** The Sterilex Corporation has submitted a rebuttal in order to support the acute toxicity requirements for their product, "Sterilex Ultra Disinfectant Cleaner Solution 1". This unique submission constitutes a complex Similarity Clinic determination. This submission does not include any actual acute toxicity studies or data (No MRIDs).

Items of concern in this toxicity review are:

- 1 Sterilex Ultra Disinfectant Cleaner Solution 1 is one part of a two part disinfectant product. According to the product label: "**Sterilex Ultra Disinfectant Cleaner Solution 1** is part one of a two-part product. This product must **ALWAYS** be used in conjunction with Sterilex Ultra Activator Solution." Thus, the user of this product will have potential exposure to three mixtures or formulations:
 - A Sterilex Ultra Disinfectant Cleaner Solution 1
 - B Sterilex Ultra Activator Solution
 - C The product that results from the mixture of the two (A and B above).
- 2 The registrants feel that they should not have to conduct acute toxicity studies on each of the three formulations (see above) involved in the use of this product.
- 3 According to the registrant, the product resulting from the combination of Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution is Substantially Similar to the product resulting from the combination of Ultra Kleen Solution 1 with Ultra Kleen Solution 2. The registrant's agent, Lewis & Harrison, states in their 11/30/2004 letter: "Therefore, we strongly urge EPA to reconsider that, under these circumstances; the acute oral toxicity, acute dermal toxicity and dermal sensitization data for Ultra Kleen Solution 1 will also support the registration of Sterilex Ultra Disinfectant Cleaner Solution 1."
- 4 According to a 10/16/98 CTT/AD review, the requirements for the acute dermal toxicity and dermal sensitization studies for Ultra Kleen Solution 1, 63761-G, were waived.

A previous review of 63761-I was conducted on 9/23/4. The results of that review were:

Study	MRID Number	Toxicity Category	Acceptability
acute oral toxicity			Data Gap
acute dermal toxicity			Data Gap
acute inhalation toxicity			Data Gap
primary eye irritation	445927-04	I	Cited
primary skin irritation	445927-05	I	Cited
dermal sensitization			Data Gap

II RECOMMENDATIONS: PSB findings are:

- 1 The request to cite acute dermal toxicity and dermal sensitization data from Ultra Kleen Solution 1 to support the registration of Sterilex Ultra Disinfectant Cleaner Solution 1 is denied. AD/OPP does not cite or bridge waivers of acute toxicity studies.

(The primary eye and skin irritation studies from 63761-3 were cited to support 63761-I. However, CTT/PSB feels that one component of the two products has a similar formulation. (Note that CTT/PSB does not say that this product is similar enough to support a complete set of acute toxicity studies.) As 63761-3 is corrosive, CTT/PSB feels that 63761-I will be corrosive too. As it will be assigned toxicity category I, its potential irritation can not be worse. Lastly, the support for these two 63761-3 studies was not done as waivers.)

- 2 CTT/PSB requests that acute oral toxicity, acute dermal toxicity and acute inhalation toxicity studies be conducted on each of the following:
 - A Sterilex Ultra Disinfectant Cleaner Solution 1
 - B Sterilex Ultra Activator Solution
 - C The product that results from the mixture of the two (A and B above).
- 3 CTT/PSB will waive the dermal sensitization study for this product if the registrant requests. As this product is assigned toxicity category I for primary skin irritation, users of the products and use-mixture are required to wear chemical-resistant gloves and protective clothing. Thus, the frequent dermal exposure needed for dermal sensitization is not expected. (This is different from a one-time dermal exposure required for acute dermal toxicity.)
- 4 CTT/PSB has not received a detailed CSF of the mixture of Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution.

Acute Toxicity Profile for File Symbol 63761-I			
Study	MRID Number	Toxicity Category	Acceptability
acute oral toxicity			Data Gap
acute dermal toxicity			Data Gap
acute inhalation toxicity			Data Gap
primary eye irritation	445927-04	I	Cited
primary skin irritation	445927-05	I	Cited
dermal sensitization			Data Gap

III LABELING: No precautionary labeling can be recommended at this time.